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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,494	02/27/2004	Kozo Tsubouchi	OPS Case 635	7999

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/789,494	TSUBOUCHI ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are allowed.
- 6) ☒ Claim(s) 3-16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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1. Claims 6, 8, 10, 12, 14, 16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if the phrase "having an amino acid sequence selected from the following amino acid sequences..." at claim 16, lines 5-6, modifies the partial peptides or the peptide chains recited earlier in the claim. Therefore, it is not clear if the partial peptides must comprise one of SEQ ID NOS:1-8, or if the partial peptides must be fragments of one of SEQ ID NOS:1-8. Claim 18 is unclear because it recites that the partial peptides can comprise as few as four amino acid residues, but SEQ ID NOS:1-8 comprise at least six amino acid residues. It is not clear if Applicants are intending to claim fragments of SEQ ID NOS:1-8 comprising as few as four amino acid residues.

2. Instant claims 3-7 and 10-16 are deemed to be entitled under 35 U.S.C. 119(a)-(d) to the benefit of the filing date of the foreign priority document, JP 2003-055048, because the foreign priority document, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

Instant claims 8, 9, 17, and 18 are not deemed to be entitled under 35 U.S.C. 119(a)-(d) to the benefit of the filing date of the foreign priority document, JP 2003-055048, because the foreign priority document, under the test of 35 U.S.C. 112, first paragraph, does not disclose cell adhesion agents, and does not disclose peptides with an upper size limit of forty amino acids.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by the Japanese Patent Application 6-292595. The Japanese Patent Application '595 teaches subjecting silk

protein from a domestic silkworm (see paragraph [0014] of the machine translation) to hydrolysis with a protease (see paragraph [0015] of the machine translation) followed by gel filtration (see paragraph [0027] of the machine translation), which is a species of molecular weight fractionation. Applicants' claim recitation "excellent for promoting cell growth" is either an inherent property of the product or an intended use limitation, and as such does not impart patentability to the method of making claims.

5. Claims 8, 9, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by the Yamada et al article (Biomaterials, Vol. 25, Issue 3, pages 467-472). The Yamada et al article teaches peptides derived from the amorphous fraction of chymotrypsin-digested fibroin. The amorphous fraction is further subjected to chromatographic fractionation. The peptides have amino acid sequences corresponding to Applicants' SEQ ID NOS:1 and 2, and enhance the proliferation of cultured human skin fibroblasts. See, e.g., the Abstract; section 2; and section 4. With respect to instant claims 8 and 9, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

The Scientific and Technical Information Center contacted the publisher of Biomaterials and was informed that the Yamada et al article was made available to the public online in August 2003. Also, the University of Virginia Health Sciences Library has a date stamp on the above issue of December 2, 2003. Accordingly, the Yamada et al article available as prior art against the instant claims under 35-U.S.C.-102(a).

6. Claims 6, 8, 10, 12, 14, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hummel et al (U.S. Patent No. 6,037,158). Hummel et al teach an isolated peptide fragment of alcohol dehydrogenase. The peptide fragment consists of 16 amino acids,

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and comprises the partial sequence DGGY, which corresponds to residues 7-10 of Applicants' SEQ ID NO:8. See Example 4. To the extent that SEQ ID NOS:1-8 of claim 16 define the peptide chains (and therefore the partial peptides can be fragments of the peptide chains/SEQ ID NOS:1-8), and to the extent that claim 18 embraces 4-mer fragments of SEQ ID NOS:1-8, the partial peptides of claims 16 and 18 can comprise an amino acid sequence of as few as four amino acids from Applicants' SEQ ID NO:8. In view of Applicants' "comprising" and "having" language, Applicants' claimed peptide compositions permit the presence of amino acids in addition to the 4-mer amino acid sequence from Applicants' SEQ ID NO:8. In view of the similarity in amino acid sequence between the peptide of Hummel et al and Applicants' claimed peptide compositions, the former are deemed inherently to have cell growth promoting properties to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the isolated peptide fragment of Hummel et al and Applicants' claimed products to shift the burden to Applicants to provide evidence that the claimed products are unobviously different than that of Hummel et al. With respect to claims 6, 8, 10, 12, and 14, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

7. Claims 3, 6-16, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Altman et al (U.S. Patent Application Publication 2005/0089552). Altman et al teach Bombyx mori silk fibroin isolated from sericin. See paragraph [0087]. In view of Applicants' "comprising" and "having" language, Applicants' claimed peptide compositions and claimed peptides are interpreted as permitting the presence of amino acids in addition to those present in peptide chains which form noncrystalline portions of silk proteins. Because the isolated silk

fibroin of Altman et al is the same source from which Applicants derive their partial peptides and peptide chains, inherently the isolated silk fibroin of Altman et al will comprise the same partial peptides and peptide chains having the same amino acid sequences as are claimed by Applicants and inherently will have cell growth promoting properties to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the isolated silk fibroin of Altman et al and Applicants' claimed peptide compositions and peptides to shift the burden to Applicants to provide evidence that the claimed products are unobviously different than that of Altman et al. With respect to claims 6-15, intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

8. Applicant's arguments filed April 4, 2006 have been fully considered but they are not persuasive.

The rejection over the Japanese Patent Application 6-292595 is maintained. Amended claim 4 does not specify from what the peptides from the noncrystalline portions of the silk proteins are to be separated, and do not specify any degree of separation. Because the peptides of the Japanese Patent Application '595 are being subjected to gel filtration, peptides from the noncrystalline portions are being separated from peptides from both the crystalline and noncrystalline portions having different molecular weights.

As set forth in section 2 above, instant claims 3-7 and 10-16 are entitled under 35 U.S.C. 119(a)-(d) to the benefit of the filing date of Applicants' foreign priority document, and accordingly the Yamada et al article (Biomaterials, Vol. 25, Issue 3, pages 467-472) is not available as prior art against these claims. The Yamada et al article is available as prior art against instant claims 8, 9, and 18, and is applied against these claims.

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The rejection over Altman et al (U.S. Patent Application Publication 2005/0089552) is maintained. Note that the effective filing date of Altman et al is November 16, 2001, and the reference can not be antedated under 35 U.S.C. 119(a)-(d).

9. Claim 17 is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

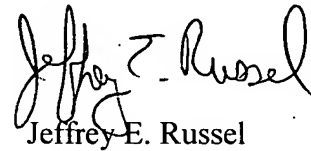
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

July 17, 2006

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